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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/247,874	02/10/1999	GORDON W. DUFF	MSA-004.01	8151

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FOLEY HOAG LLP
PATENT GROUP
155 SEAPORT BOULEVARD
BOSTON, MA 02110

EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/247,874

Applicant(s)

DUFF ET AL.

Examiner

Richard Schnizer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34 and 46-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34, 51 and 52 is/are allowed.
- 6) ☒ Claim(s) 46-50 and 53-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>29</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/8/02 has been entered.

An amendment was received and entered as Paper No. 26 on 2/8/02. Previously allowed claims 35 and 45 were canceled, and claims 46-57 were added. Claims 34 and 46-57 are pending and under consideration in this Office Action.

Oath/Declaration

The Oath submitted 2/8/02 and entered as Paper No. 27 is objected to because it adds a new inventor (Kenneth Kornman) but fails to comply with any of the requirements of 37 CFR 1.48(a) (1-5) which is reproduced below.

§ 1.48 Correction of inventorship in a patent application, other than a reissue application, pursuant to 35 U.S.C. 116.
(a) Nonprovisional application after oath /declaration filed . If the inventive entity is set forth in error in an executed § 1.63 oath or declaration in a nonprovisional application, and such error arose without any deceptive intention on the part of the person named as an inventor in error or on the part of the person who through error was not named as an inventor, the inventorship of the nonprovisional application may be amended to name only the actual inventor or inventors. If the nonprovisional application is involved in an interference, the amendment must

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comply with the requirements of this section and must be accompanied by a motion under § 1.634. Amendment of the inventorship requires:

- (1) A request to correct the inventorship that sets forth the desired inventorship change;
- (2) A statement from each person being added as an inventor and from each person being deleted as an inventor that the error in inventorship occurred without deceptive intention on his or her part;
- (3) An oath or declaration by the actual inventor or inventors as required by § 1.63 or as permitted by §§ 1.42, 1.43 or § 1.47;
- (4) The processing fee set forth in § 1.17(i); and
- (5) If an assignment has been executed by any of the original named inventors, the written consent of the assignee (see § 3.73(b) of this chapter).

Appropriate action is required.

Compliance with Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s). The sequence of SEQ I DNO:2 disclosed in the CRF does not match that of SEQ I DNO:2 as disclosed in the paper copy of the Sequence Listing. Specifically, position 8845 is listed as a C residue in the CRF, but is a G residue in the paper copy. Applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

Applicant must provide:

An substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

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A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-50, 53-55 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al (Nature 377 (suppl): 3-174), as evidenced by Brummet et al (US Patent No. 5,719,056).

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Adams teaches an expressed sequence tag comprising 55 bases identical to bases 8795-8849 of SEQ ID NO: 2. See attached sequence alignment. This sequence was initially contained in the double stranded vector Lambda Zap II. See page 4, column 2, second full paragraph. For this reason the isolate contained the complement recited in claim 53. The nucleic acid was sequenced using PRISM Ready Reaction Dye Primers, resulting in molecules containing fluorescent labels. For evidence that these labels are fluorescent, see Brummet, column 2, lines 53-57. Claim 57 is included in this rejection because the metes and bounds of "part of a probe array" are considered to embrace the ESTs of Adams. The specification does not give a limiting definition to the term "probe array", although that it is clear that this term is intended to encompass solid supports to which an array of individual probes is bound. Because specification does not limit the scope of "probe array" so it has been given its broadest reasonable interpretation. For example, "probe array" could also refer in the abstract to a group of probes that would be recognized as useful for some purpose, but which are not physically grouped together in an array on a DNA chip. For example, one might recognize that a particular group of probes might be useful for forensic analysis of tissue samples. This group of a probes could be considered to be a probe array, even if the probes were never assembled into a physically contiguous array. Adam's a set of 174, 472 ESTs which can be thought of as a collection of probes useful for cloning genes in the human genome. See abstract.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams in view of Maniatis et al (1982) and Leary et al (Proc. Nat. Acad. Sci (1983) 80(13): 4045-4049).

Adams teaches an expressed sequence tag comprising 55 bases identical to bases 8795-8849 of SEQ ID NO: 2. See attached sequence alignment. This sequence is an incomplete cDNA which corresponds to a gene expressed in human macrophages. The objective of Adams was to identify all of the genes in the human genome. Hence it would have been obvious to one of ordinary skill in the art to use the incomplete cDNA to isolate a complete cDNA and a genomic clone. One would have been motivated to do so as part of doing so, it would have been obvious to use art-recognized procedures such as generating libraries of genomic or cDNA sequences, attaching them to solid supports, and screening them by hybridization with radiolabeled versions of the incomplete cDNA of Adams. Such procedures are detailed by Maniatis. See e.g. pages 313-315. In making cDNA libraries, it would have been obvious to attach isolated mRNAs to magnetic, metal-binding beads in order to facilitate purification, as

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suggested by Adams. See page 4, column 2, second full paragraph. Leary teaches improved methods of detecting hybridized nucleic acid probes wherein a biotinylated probe is bound by a complex of avidin or streptavidin and biotinylated alkaline phosphatase, providing a nucleic acid comprising biotin, avidin (or streptavidin), and an antigenic enzyme.

Thus the invention as a whole was *prima facie* obvious.

Conclusion


Claims 34, 51 and 52 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.


JAMES KETTER
PRIMARY EXAMINER